SEP 2 0 2001

K 011223

ADMINISTRATIVE INFORMATION

Manufacturer Name: Quantum BioEngineering, Ltd.
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Telephone (858) 792-1235
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DEVICE NAME

Classification Name: Endosseous dental implant

Trade/Proprietary Name: Quantum™ Versatility™ (QVS™) Dental Implant System

Common Name: Dental Implant

ESTABLISHMENT REGISTRATION NUMBER

Quantum BioEngineering, Ltd. is not yet registered with FDA.

DEVICE CLASSIFICATION

Endosseous dental implants have been classified by FDA as Class III devices under a final order published in the Federal Register of August 12, 1987, as shown in 21 CFR 872.3640. Abutments to such implants are considered by FDA to be Class III devices inasmuch as they are attached to and form part of endosseous dental implants. The device is reviewed by the Dental Products Panel and the Product Code for the device is DZE.

CONFORMANCE WITH PERFORMANCE STANDARDS

No performance standards have been established under Section 514. Voluntary standards with which the Quantum Versatility Dental Implant System complies include American Society for

Testing and Materials (ASTM) designation F-136 (Standard Specification for Wrought Titanium 6Al-4V ELI Alloy for Surgical Implant Applications.

PACKAGING/LABELING/PRODUCT INFORMATION

Advertising material to be used for promotion of the Quantum Versatility Dental Implant System will be consistent with the indications for use and other material shown herein.

Quantum abutments are sold either sterile or non-sterile. If sterile, they will be packaged in a radiation sterilizable package consisting of an outer tamper evident container (e.g., a printed cardstock sleeve enclosing a vacuum formed tray with a heat sealed Tyvek lid) and an inner plastic bag. Sterilization will be accomplished by means of Co^{60} gamma irradiation at a dose of 25 kGy (2.5 Mrad) minimum. Sterilization will be validated by the bioburden method. The sterility assurance level (SAL) that Quantum intends to meet is 10^{-6}. If sold non-sterile, abutments will be packaged in plastic bags. The device is not represented to be "pyrogen free."

INTENDED USE

Quantum abutments are intended for attachment to Quantum Versatility dental implants for the support of single or multiple-tooth prostheses including fixed or removable complete dentures. The Quantum Versatility Dental Implant System is intended for implantation into a partially or fully edentulous mandible or maxilla for the support of single or multiple-tooth prostheses including fixed or removable complete dentures.

DEVICE DESCRIPTION

Design Characteristics

The Quantum Versatility Dental Implant System is composed of both threaded (screw-type) and grooved (fin-type) tapered implants and transmucosal elements (abutments) that attach to the implant with a modified Morse taper connection and are intended to be used as abutments for prosthetic restoration. Premarket Notifications K991250 and K002241, previously submitted by Quantum to FDA, include threaded and grooved implants and straight abutments. The subject of this Premarket Notification is a series of transmucosal elements (abutments), including premanufactured angled abutments, either with an external Morse taper for insertion into the internal Morse taper of the implant, or with with internal hex features, intended to be attached to the implant by means of screws. The preangled abutments correct for misangulation that might occur during surgical placement of implants. This Notification also includes a fixture mount that is intended to facilitate the insertion of the implant into bone, but which also may be used as an abutment for prosthetic restoration. Additional components covered by this submission include healing plugs and caps (including a polyethylene plug that can be cut to length, as well as single-stage and two-stage titanium plugs and caps), copings, abutments for fixed (screw-retained)

restorations, O-ring abutments, inverted O-ring abutments, conical abutments with O-ring retaining grooves (fixed-removable), universal abutments that retain a cemented coping, and universal preparable abutments for correcting misangulated implant positioning,

Material Composition

Implants and abutments for the Quantum Versatility Dental Implant System are made from titanium-aluminum-vanadium alloy that meets ASTM designation F-136 (Standard Specification for Wrought Titanium 6Al-4V ELI Alloy for Surgical Implant Applications). The use of titanium and titanium alloy is widespread in commercially distributed, permanently implanted medical devices and the materials are widely considered to be biocompatible. Titanium is often used as a negative control in biocompatibility testing.

EQUIVALENCE TO MARKETED PRODUCT

Quantum BioEngineering, Ltd. submits the following information and Exhibits to demonstrate that the included components of the Quantum Versatility Dental Implant System are substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices, including the Bicon Dental Implant (K853788, K875243, K875242), Steri-Oss Replace HA-Coated implant (K962845), Simpler Threaded Implant (K974401, K974402, K974856, K974857), Astra Tech Implant - Dental System (K990304), the ERA attachment for the Sterngold / Impla-Med implant system, and the Brånemark Fixture (K925765, K934825). Product information on the predicate devices is contained in Exhibit IV.

Intended Uses

The indications for use for the subject components of the Quantum Versatility Dental Implant System and the predicate devices are substantially the same. All are intended for attachment to dental implants for the support of single or multiple-tooth prostheses including fixed or removable complete dentures.

Design and Materials

The design and functional characteristics of the Quantum Versatility Dental Implant System and the Bicon Dental Implant are similar in their use of a tapered, grooved implant design and a Taper Lock (modified Morse taper) connection between the implant and abutment. The Quantum Taper Lock Angled Abutment is similar to angled abutments of the Bicon Dental Implant System. The Quantum preangled hexed abutments are similar to preangled abutments marketed by Nobel Biocare (Brånemark System, Steri-Oss), Implant Innovations, Inc., and numerous other dental implant manufacturers. Similarities between the other components of the Quantum Versatility Implant System and the predicate devices are shown in the Summary: Table of Substantial Equivalence, below. The Quantum implant system shares the use of Ti-6Al-4V with all the

predicate devices except the Steri-Oss and Brånemark implants, as well as with numerous other marketed implants.

Mechanical Testing of Angled Abutments Attached to Quantum Dental Implants

In order to determine the strength of angled abutments of the Quantum Versatility Implant System, static and cyclic compression bending tests were conducted.

SUMMARY: TABLE OF SUBSTANTIAL EQUIVALENCE

The subject components of the Quantum Versatility Dental Implant System are substantially equivalent to components of Bicon Dental Implant, Steri-Oss Replace HA-Coated Implant, Simpler Threaded Implant, Astra Tech implant system, Sterngold / Impla-Med implant system and the Brånemark Fixture in the following respects:

	Subject Device	Predicate Devices					
	Quantum Versatility Dental Implant System	Bicon Dental Implant (K853788, K875243, K875242)	Steri-Oss Replace HA-Coated Implant (K962845)	Simpler Threaded Implant (K974401, K974402, K974856, K974857)	Astra Tech Implant - Dental System (K990304)	Sterngold/ Impla-Med	Brånemark Fixture (K925765, K934825)
INTENDED USE							
Attachment to a dental implant for the support of single or multiple-tooth prostheses including fixed or removable complete dentures.	YES	YES	YES	YES	YES	YES	YES
DESIGN FEATURE							
Preangled abutment with modified Morse taper	YES	YES		YES	YES		
Preangled hexed screw-retained abutment	YES		YES			YES	YES
Maximum angle of preangled abutments	25°	25°			30°	30°	30°
Resilient attachment system for overdentures	YES	YES	YES	YES	YES		YES
Inverted resilient attachment system for overdentures	YES					YES	
Preparable universal abutment	YES				YES		YES
MATERIAL							
Abutments	Ti-6Al-4V	Ti-6Al-4V	Ti alloy	Ti-6Al-4V	CP Ti	Ti	CP Ti

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 0 2001

Mr. Floyd G. Larson
Consultant
Paxmed International
4329 Grayton Road
San Diego, California 92130

Re: K011223
Trade/Device Name: Quantum Versatility (QVS) Dental Implant System
Regulation Number: 872.3640
Regulatory Class: III
Product Code: DZE
Dated: April 18, 2001
Received: April 20, 2001

Dear Mr. Larson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: Components of the Quantum™ Versatility Dental Implant System K011223

Indications for Use:

Intended for attachment to Quantum Versatility dental implants for the support of single or multiple-tooth prostheses including fixed or removable complete dentures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011223